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|                             | •               |                         |                     |                  |
|-----------------------------|-----------------|-------------------------|---------------------|------------------|
| APPLICATION NO. FILING DATE |                 | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/045,917                  | 01/09/2002      | Kendell Simm            | SIMM-CIPI           | 4732             |
| 5                           | 7590 12/22/2003 | EXAMINER                |                     |                  |
| Curt Harringt               | ton             | MOHANDESI, ЛLА М        |                     |                  |
| Suite 250<br>6300 State Uni | iversity Drive  | ART UNIT                | PAPER NUMBER        |                  |
| Long Beach, (               |                 | 3728                    |                     |                  |
|                             |                 | DATE MAILED: 12/22/2003 |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary  |   |                  | Application No. Applicant(s) |   |             |      |  |  |  |
|--|---|------------------|------------------------------|---|-------------|------|--|--|--|
|  |   |                  | 10/045,917                   |   | SIMM ET AL. |      |  |  |  |
|  |   |                  | Examiner                     |   | Art Unit    |      |  |  |  |
| <u>-</u>   |   |                  | Jila M Moha                  | ndesi   | 3728        | 12   |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |   |                  |                              |   |             |      |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status  |   |                  |                              |   |             |      |  |  |  |
| 1)⊠  | Responsive to communication(s) filed  | on <u>31 Oct</u> | <u>ober 2003</u> .           |   |             |      |  |  |  |
| 2a)⊠   | This action is <b>FINAL</b> . 2b) This action is non-final.   |                  |                              |   |             |      |  |  |  |
| 3)□  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |                  |                              |   |             |      |  |  |  |
| Disposition of Claims  |   |                  |                              |   |             |      |  |  |  |
| 4)⊠  | 4)⊠ Claim(s) <u>1-19</u> is/are pending in the application.   |                  |                              |   |             |      |  |  |  |
|  | 4a) Of the above claim(s) is/are withdrawn from consideration.  |                  |                              |   |             |      |  |  |  |
| 5)   | Claim(s) is/are allowed.  |                  |                              |   |             |      |  |  |  |
| ·  | ☑ Claim(s) <u>1-19</u> is/are rejected.   |                  |                              |   |             |      |  |  |  |
|  | Claim(s) is/are objected to.  |                  |                              |   |             |      |  |  |  |
| 8)∐  | Claim(s) are subject to restriction   | on and/or e      | election red                 | luirement.  |             |      |  |  |  |
| Applicati  | on Papers   |                  |                              |   |             |      |  |  |  |
| • • • •  | The specification is objected to by the   |                  |                              |   |             |      |  |  |  |
| 10)⊠   | The drawing(s) filed on 31 October 200  |                  | ,                            |   | •           | ner. |  |  |  |
| •  | Applicant may not request that any objecti  |                  |                              | <u>-</u>  |             |      |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |                  |                              |   |             |      |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                  |                              |   |             |      |  |  |  |
|  | ınder 35 U.S.C. §§ 119 and 120  |                  |                              |   |             |      |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No.  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.  37 CFR 1.78.  a) The translation of the foreign language provisional application has been received.  14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78. |   |                  |                              |   |             |      |  |  |  |
| Attachmen  |   |                  |                              | . 🗖   |             |      |  |  |  |
| 2) Notic   | e of References Cited (PTO-892)<br>e of Draftsperson's Patent Drawing Review (PT0<br>mation Disclosure Statement(s) (PTO-1449) Pap  |                  | 5                            | Interview Summary     Notice of Informal P     Other: . |             |      |  |  |  |

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#### **DETAILED ACTION**

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## Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1-5, 8-9, 11, 13 and 16-18 are rejected under 35 U.S.C. 103(a) as being obvious over Sagstetter (5,409,112) in view of Seeley (3,746,155). Sagstetter `112 discloses a hypodermic needle holder for safely storing and disposing of a hypodermic needle, and comprising: a body portion and a lid portion (3, 4) connected to said body portion and a main opening lockably coverable by said lid portion, (inasmuch as applicant has defined the main opening the reduction in surface of the holder does in fact constitute a main opening) there are at least a plurality of needle retaining openings (35, 50, 5) in communication with said main opening for frictionally engaging and retaining said hypodermic needle by at least frictional engagement upon insertion of said hypodermic needle within said needle retaining opening; and support structure. connected to said body portion, for enabling said hypodermic needle holder to be stably supported and utilized for frictionally engaging and retaining said hypodermic needle without manual grasping. See Figure 2 embodiment. Sagstetter `112 does not appear to teach each needle retaining opening associated with and in communication with an isolated chamber. Seeley `155 discloses a hypodermic needle holder having a plurality of needle retaining openings associated with and in communication with isolated

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chambers for better sorting and separating the items being disposed.(see Figure 3 embodiment and column 1, lines 41-42).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide isolated chambers associated with each needle retaining openings of Sagstetter `112 as taught by Seeley `155 to better sort and separate the items being disposed therein.

With respect to claim 3, note the raised projection on the lid (latch in Figure 2 embodiment) which engages and fits within said main opening.

With respect to claim 5, see Figure 3 embodiment which will frictionally engage and retain a hypodermic needle.

With respect to claim 8, note the container 5, in Figure 2 embodiment.

With respect to claim 9 which further limits the shape of the container, this would be a design choice depending on the size and make of the hypodermic syringe and the routine optimization expected by one of ordinary skill in the art.

With respect to claim 11, Official Notice is taken that it is old and conventional to provide a layer of adhesive to holders for enhancing the upright stability of the holder.

With respect to claim13 which further limits the material of the holder, this would be a design choice since, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 16-18 are directed to the obvious method of using the hypodermic needle holder of Sagstetter `112 comprising the steps of:

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a) Affixing a hypodermic needle holder to an object;

b) Advancing a hypodermic needle supported by a hypodermic syringe into said opening;

- c) Frictionally engaging said hypodermic needle to said needle retainer;
- d) De-coupling said hypodermic needles from said needle and inhibit its cross contamination; and removing said hypodermic syringe away from said opening.

## Allowable Subject Matter

3. Claims 6-7, 10, 12, 14 –15 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

## Response to Arguments

4. Applicant's arguments filed October 31, 2003 have been fully considered but they are not persuasive.

In response to applicant's argument that the instant application is for temporary storage of a used or new needle or permanent disposal of needles which have been used as well as isolation of each needle, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

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In response to applicant's argument that in makes no sense to combine the teachings of the above references, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

#### Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jila M Mohandesi whose telephone number is (703) 305-7015. The examiner can normally be reached on Monday-Friday 7:30-4:00 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (703) 308-2672. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

JILA M. MOHANDESI PRIMARY EXAMINER

Jila M Mohandesi Primary Examiner Art Unit 3728

JMM December 17, 2003